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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
PAK, MICHAEL D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,159	JEGLA ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 22, 23, drawn to nucleic acids corresponding to SEQ ID NOS: 3 and 4, expression vectors comprising same, and host cells comprising same, classified in class 435, subclass 252.3, for example.

II. Claim 11, drawn to method of detecting a nucleic acid corresponding to SEQ ID NO: 4, classified in class 435, subclass 6.

III. Claims 12-19, drawn to polypeptides corresponding to SEQ ID NO: 4, classified in class 530, subclass 350.

IV. Claims 20-21, drawn to antibodies that bind polypeptides corresponding to SEQ ID NO: 4, classified in class 530, subclass 387.1.

V. Claims 24-33, drawn to method for identifying a compound that increases or decreases ion flux through a potassium channel comprising contacting a polypeptide corresponding to SEQ ID NO: 4 with a compound, classification dependent upon structure of recited compound.

VI. Claim 34, drawn to method of identifying compounds that affect ion flux using a polypeptide corresponding to SEQ ID NO: 4 and a computer system, classification dependent upon structure of recited compound.

VII. Claim 35, drawn to therapeutic method comprising administering a compound that affects ion flux of a channel comprising a polypeptide

corresponding to SEQ ID NO: 4, classification dependent upon structure of recited compound.

VIII. Claims 36 and 37, drawn to method of detecting the presence of a polypeptide corresponding to SEQ ID NO: 4, classified in class 435, subclass 7.1, for example.

IX. Claims 38 and 39, drawn to method of screening for mutations in a polypeptide corresponding to SEQ ID NO: 4 using a computer system, classified in class 702, subclass 19.

X. Claims 40-45, 53 and 54, drawn to nucleic acids corresponding to SEQ ID NOS: 1 and 2, expression vectors comprising same, and host cells comprising same, classified in class 435, subclass 252.3, for example.

XI. Claim 46, drawn to method of detecting a nucleic acid corresponding to SEQ ID NO: 2, classified in class 435, subclass 6.

XII. Claims 47-51, drawn to polypeptides corresponding to SEQ ID NO: 2, classified in class 530, subclass 350.

XIII. Claim 52, drawn to antibody that binds polypeptides corresponding to SEQ ID NO: 2, classified in class 530, subclass 387.1.

XIV. Claims 55-63, drawn to method for identifying a compound that increases or decreases ion flux through a potassium channel comprising contacting a polypeptide corresponding to SEQ ID NO: 2 with a compound, classification dependent upon structure of recited compound.

XV. Claim 64, drawn to method of identifying compounds that affect ion flux using a polypeptide corresponding to SEQ ID NO: 2 and a computer system, classification dependent upon structure of recited compound.

XVI. Claim 65, drawn to therapeutic method comprising administering a compound that affects ion flux of a channel comprising a polypeptide corresponding to SEQ ID NO: 2, classification dependent upon structure of recited compound.

XVII. Claims 66, 67, drawn to method of detecting the presence of a polypeptide corresponding to SEQ ID NO: 2, classified in class 435, subclass 7.1, for example.

XVIII. Claims 68, 69, drawn to method of screening for mutations in a polypeptide corresponding to SEQ ID NO: 4 using a computer system, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Claims 1-39 are nearly identical to claims 40-69 with the exception that claims 1-39 recited the polypeptide of SEQ ID NO: 4 whereas claims 40-69 recite the polypeptide of SEQ ID NO: 2. These claims are independent and distinct because a search for inventions reciting SEQ ID NO: 4 would be non-coextensive with the search for inventions reciting SEQ ID NO: 2. An independent search must be performed of all literature and sequence databases for each sequence. Therefore, examination of all

inventions reciting either sequence would present the USPTO with an undue search burden.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I, III, IV, X, XII and XIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the proteins of Groups III and XII can be prepared by processes which are materially different from recombinant DNA expression of Groups I and X, respectively, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Groups III and X can be used other than to make the proteins of Group III and XII, respectively, such in gene therapy or as a probe in nucleic acid hybridization assays. The proteins of Group III and XII can be used in materially different methods other than to make the antibodies of Groups IV and XIII, respectively, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibodies of Groups IV and XIII can be used to obtain the DNAs of Groups III and X, respectively, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to

constitute patentably distinct inventions for the following reasons: Groups II, V-IX, XI, XIV-XVIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention II requires detection of nucleic acids corresponding to SEQ ID NO: 4, which is not required by any of the other groups. Invention V requires identification of compounds that affect ion flux of SEQ ID NO: 4 via a protein assay, which is not required by any of the other groups. Invention VI requires identification of compounds that affect ion flux of SEQ ID NO: 4 via computer modeling, which is not required by any of the other groups. Invention VII requires administration of compounds affecting ion flux of SEQ ID NO: 4, which is not required by any of the other groups. Invention VIII requires detection of SEQ ID NO: 4, which is not required by any of the other groups. Invention IX requires screening for mutations in SEQ ID NO: 4 using computer modeling, which is not required by any of the other groups. Invention XI requires detection of nucleic acids corresponding to SEQ ID NO: 2, which is not required by any of the other groups. Invention XIV requires identification of compounds that affect ion flux of SEQ ID NO: 2 via a protein assay, which is not required by any of the other groups. Invention XV requires identification of compounds that affect ion flux of SEQ ID NO: 2 via computer modeling, which is not required by any of the other groups. Invention XVI requires administration of compounds affecting ion flux of SEQ ID NO: 2, which is not required by any of the other groups. Invention XVII requires detection of SEQ ID NO: 2, which is not required by any of the other groups. Invention XVIII requires screening for mutations in SEQ ID NO: 2 using computer modeling, which is not required by any of the other groups. Therefore, a search and examination of all of

the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I and II, as well as inventions X and XI, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used to produce the encoded proteins recombinantly in vitro.

Inventions III and each of V, VI, VIII and IX; as well as inventions XII and each of XIV, XV, XVII and XVIII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins can be used to generate antibodies, or to isolate their binding partners.

Each of the remaining pairs of inventions are product/method pairs. However, each pair is independent and distinct because, for each pair of inventions, the method does not require use of the product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, Ph.D., whose telephone number is (703) 305-7038.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER